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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,449	07/13/2001	Avi Ashkenazi	10466/58	1667
9157	7590	11/10/2003	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			MOSHER, MARY	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/905,449	Applicant(s) ASHKENAZI ET AL.	
	Examiner Mary E. Mosher, Ph.D.	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 44-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment after final rejection, filed 10/14/2003, has been entered. Finality has been withdrawn to make a new ground of rejection for claim 51.

### ***Claim Rejections - 35 USC § 102***

Claims 44-46 and 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al 5,942,606. Claims 44-46 and 49-50 remain rejected for reasons of record. Claim 51 is added to the rejection, because on reconsideration it was noted that Lal teaches an epitope tagged fusion polypeptide, see column 12, lines 38-44.

### ***Response to Arguments***

Applicant argues that the publications by McNicholl and Struyf deal with altering a naturally occurring receptor, not comparing two different receptors, and therefore are not probative of whether a viral receptor must be highly homologous to CAR in order to be functional. However, applicant relies entirely upon similarity in structure to CAR to infer function and usefulness as a viral receptor in the disclosure on the claimed priority date. The cited art is very relevant because it addresses the issue of the relationship between structure and function for virus receptors, and it teaches that minor changes in structure (truncation, alteration) can have major effects upon function in a virus receptor protein. Applicant's naturally occurring protein has larger changes in structure compared to the most similar known virus receptor, and therefore the unsupported assertion of function as a virus receptor (based upon the degree of similarity in structure) would not be unquestioningly accepted by those skilled in the art.

Applicant argues that the prior art, specifically Tomko et al page 3352, provides a general virus assay. The examiner fails to see where Tomko provides evidence of general knowledge in the art of a routine assay to discover an actual virus which can bind to a hypothetical receptor. Tomko was working with known viruses and a functionally defined receptor, obtaining a nucleic acid encoding the receptor and determining the structure of the nucleic acid and protein receptor. Here applicant has defined a structure and sought, as of the claimed priority date, to infer similarity in function based upon a modest similarity in structure to a known virus receptor CAR. The previous rejections provide sound scientific reasons to doubt that asserted function, because the regions most similar to the virus receptor CAR are found in a nonessential region of CAR, and the region of CAR which functions by interacting with a virus shows little or no similarity to applicant's sequence. Even if the protein actually can act as a receptor for some virus, the priority document does not identify any specific virus which interacts with the putative receptor, requiring those skilled in the art to perform experimentation to discover a specific use for this specific protein.

Applicant argues that "To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate," and points out that the disclosure in Lal is very similar to the disclosure in the priority document. Without commenting at all on the validity of patent 5,942,606, the examiner notes that the facts in the cited case law all involve the "how-to-make" aspect of enablement, where the issue is whether or not the asserted prior art put the claimed product in the possession of the public. An

anticipatory reference is not required to even disclose a use for a product, see *In re Schoenwald* (CAFC) 22 USPQ 1671.

***Conclusion***

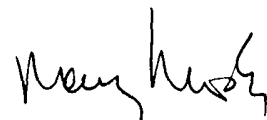
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for all official responses is now 703-872-9306.

Effective January 2004, the phone number for examiner Mosher will be (571) 272-0906, and for SPE Housel will be (571) 272-0902.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

11/7/03

  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800  
1600